U. S. Department of Energy

Environmental Management Consolidated Audit Program

Module 5

Checklist for Laboratory Information Management Systems Electronic Data Management

Revision 2
February 17, 2004

Audit ID:

Item	Line of Inquiry	Status	Summary of Observations/Objective Evidence Reviewed/Audit Notes
1.1	**Personnel**		
1.1.1	The LIMS and electronic data management support staff and users have adequate education, training and experience to perform assigned LIMS and electronic data management functions. *(EPA 2185, 8.2.1, Quality Systems for Analytical Services, 10.6e)*		
1.1.2	Job descriptions, resumes, qualifications and training for the LIMS and electronic data management support staff are current. *(EPA 2185, 8.2.2, Quality Systems for Analytical Services, 10.6e)*		
1.1.3	Quality Assurance personnel are separate from and independent of LIMS and electronic data management personnel. *(EPA 2185, 8.3.1, Quality Systems for Analytical Services, 10.6e)*		

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1.2	**LIMS Data**		
1.2.1	Periodic inspections of the LIMS operations are performed by the Quality Assurance Unit to ensure the integrity of LIMS data. The Quality Assurance Unit maintains records of inspections and submits reports to laboratory management noting any problems identified with LIMS data processing stating the corrective actions taken. *(EPA 2185, 8.3.3, 8.3.5, 8.3.6, Quality Systems for Analytical Services, 10.6e)*		
1.2.2	Individuals responsible for entering and recording data into the LIMS are uniquely identified when the data are recorded, and the times and dates are documented. *(EPA 2185, 8.4.2, Quality Systems for Analytical Services, 10.6e)*		
1.2.3	The instrument transmitting data to the LIMS is uniquely identified when the data are recorded, and the time and date are documented. *(EPA 2185, 8.4.3, Quality Systems for Analytical Services, 10.6e)*		

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1.2.4	Documentation for changes made to data in the LIMS includes: • the original recorded required documentation; • clear evidence that a change was made; • the reason for the change; • the date of the change; • the person who made the change; and, • the person who authorized the change. *(EPA 2185, 8.4.5, Quality Systems for Analytical Services, 10.6e)*		
1.3	**Software**		
1.3.1	Software Change Control documentation identifies: • persons requesting and authorizing software changes; • requirements to be met by the change; • measures for testing and quality assurance; • methods for moving changed versions to the production environment; • change request forms/problem reports; and, • priority of change requests. *(EPA 2185, 8.5.1.3, Quality Systems for Analytical Services, 10.6e)*		

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1.3.2	Documents available in the laboratory to demonstrate the validity of software used in the LIMS include: • software description and functional requirements; • listing of algorithms and formulas; • testing and quality assurance documentation; and, • installation, operation, and maintenance records. *(EPA 2185, 8.5.2.1, 8.5.2.2, Quality Systems for Analytical Services, 10.6e)*		
1.3.3	The software historical files of all versions of software programs exist and include dates that software was placed into and removed from production. *(EPA 2185, 8.5.1.5, 8.5.4, Quality Systems for Analytical Services, 10.6e)*		
1.4	**Security**		
1.4.1	Individual user names and passwords have been implemented on the LIMS. *(EPA 2185, 8.6, Quality Systems for Analytical Services, 10.6e)*		

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1.4.2	Passwords are changed regularly. *(EPA 2185, 8.6, Quality Systems for Analytical Services, 10.6e)*		
1.4.3	Users are trained in computer awareness security. *(EPA 2185, 8.6, Quality Systems for Analytical Services, 10.6e)*		
1.4.4	Operating system privileges and file access safeguards are implemented to restrict the use of LIMS data to users with authorized access. *(EPA 2185, 8.6, Quality Systems for Analytical Services 10.6e)*		
1.4.5	System events such as logon failures or break-in attempts are monitored. *(EPA 2185, 8.6, Quality Systems for Analytical Services 10.6)*		

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1.4.6	The LIMS is protected by application-specific safeguards. *(EPA 2185, 8.6, Quality Systems for Analytical Services 10.6e)*		
1.4.7	The LIMS is protected from the introduction of computer viruses. *(EPA 2185, 8.6, Quality Systems for Analytical Services 10.6)*		
1.4.8	System backups occur on a regular and published schedule and can be performed by more than one person within an organization. *(EPA 2185, 8.6, Quality Systems for Analytical Services 10.6e)*		
1.4.9	Physical access to the LIMS is limited by security measures such as locating the system within a secured facility or room, and/or utilizing cipher locks or key cards. *(EPA 2185, 8.6, Quality Systems for Analytical Services 10.6e)*		

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1.5	**Hardware**		
1.5.1	A description of the LIMS design and capacity is documented and maintained. *(EPA 2185, 8.7.1, Quality Systems for Analytical Services 10.6e)*		
1.5.2	Documentation of the regularly scheduled maintenance for LIMS hardware and communications components is maintained and includes: • descriptions of operations performed; • names of persons who conducted them; • dates operations were performed; and, • results. *(EPA 2185, 8.7.3, Quality Systems for Analytical Services 10.6)*		

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1.5.3	Documentation for repair of malfunctioning or inoperable LIMS hardware and communications components is maintained and includes: • a description of the problem; • corrective action taken; • acceptance testing criteria; and, • testing performed to ensure proper performance prior to returning the LIMS hardware to production. *(EPA 2185, 8.7.3, Quality Systems for Analytical Services 10.6e)*		
1.6	**Facilities**		
1.6.1	The LIMS is located in a temperature-controlled environment with adequate ventilation. *(EPA 2185, 8.10.1, Quality Systems for Analytical Services 10.6e)*		
1.6.2	The LIMS and associated communications components are protected through the use of surge protectors and connection to an uninterrupted power supply. *(EPA 2185, 8.10.1, Quality Systems for Analytical Services 10.6)*		

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1.6.3	Fire protection devices are available to protect the LIMS from fire. *(EPA 2185, 8.10.1, Quality Systems for Analytical Services 10.6e)*		
1.6.4	Environmentally adequate storage space is provided for the retention of LIMS data storage media and hard copy records. Long-term archival of LIMS backup media are stored in an offsite location with the same environmental control and security systems required of onsite storage facilities. *(EPA 2185, 8.10.2, Quality Systems for Analytical Services 10.6e)*		
1.7	**Standard Operating Procedures**		
1.7.1	The Quality Assurance Unit is responsible for ensuring that no deviations from approved SOPs were made without proper authorization and documentation. *(EPA 2185, 8.3.4, Quality Systems for Analytical Services, 10.6e)*		

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1.7.2	A SOP exists for how LIMS raw data are to be entered in, processed, maintained, or reported by the LIMS. *(EPA 2185, 8.4.1, Quality Systems for Analytical Services 10.6e)*		
1.7.3	A SOP exists to verify and document the accuracy of LIMS Raw Data. *(EPA 2185, 8.4.4, Quality Systems for Analytical Services, 10.6e)*		
1.7.4	A SOP exists for making changes to LIMS Raw Data. *(EPA 2185, 8.4.5, Quality Systems for Analytical Services 10.6e)*		
1.7.5	A SOP exists for software development methodologies that are based on the size and nature of the software being developed. *(EPA 2185, 8.5.1.1, Quality Systems for Analytical Services, 10.6)*		

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1.7.6	A SOP exists for testing and quality assurance methods to ensure that all LIMS software accurately performs its intended functions. The SOP includes: • acceptance criteria; • tests to be used; • personnel responsible for conducting the tests; • documentation of test results; and, • test review and approval. *(EPA 2185, 8.5.1.2, Quality Systems for Analytical Services 10.6e)*		
1.7.7	A SOP exists for software change control methods that include instructions for requesting, testing, approving, documenting, and implementing changes. *(EPQ 2185, 8.5.1.3, Quality Systems for Analytical Services, 10.6)*		
1.7.8	A SOP exists for software version control methods that document the LIMS software version currently used. Data sets are documented with the date and time of generation and/or the LIMS software version used to generate the data set. *(EPA 2185, 8.5.1.4, Quality Systems for Analytical Services 10.6e)*		

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1.7.9	A SOP exists for maintaining a historical file of software, software operating procedures, software changes, and software version numbers. *(EPA 2185, 8.5.1.5, Quality Systems for Analytical Services 10.6e)*		
1.7.10	All SOPs and LIMS documentation are readily available in the facility where the software is used and where the procedures are performed. *(EPA 2185, 8.5.3 Quality Systems for Analytical Services 10.6e)*		
1.7.11	Emergency, backup, disaster recovery, and contingency plans exist for the LIMS. *(EPA 2185, 8.6, Quality Systems for Analytical Services 10.6)*		
1.7.12	A SOP exists for defining the acceptance criteria, testing, documentation, and approval required for changes to LIMS hardware and communications components. *(EPA 2185, 8.7.2, Quality Systems for Analytical Services 10.6e)*		

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1.7.13	A SOP exists for adequately testing, inspecting and maintaining the LIMS. *(EPA 2185, 8.7.3, Quality Systems for Analytical Services 10.6e)*		
1.7.14	A SOP exists for the retention of LIMS Raw Data, documentation, and records pertaining to the LIMS. *(EPA 2185, 8.9, Quality Systems for Analytical Services 10.6e)*		
1.7.15	Standard Operating Procedures are periodically reviewed at a frequency adequate to ensure that they accurately describe the current procedures. *(EPA 2185, 8.11.2, Quality Systems for Analytical Services 10.6)*		
1.7.16	A SOP exists for creating electronic data deliverables.		

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1.7.17	A SOP exists for verifying that electronic data deliverables match hardcopy report forms (for clients requiring both).		
1.7.18	A SOP exists for handling and documenting client-requested modifications to electronic data deliverable formats.		
1.8	**Electronic Data Deliverables**		
1.8.1	The hardcopy data reporting forms and electronic data deliverables are created from the same source.		
1.8.2	A corrective action plan exists for resolving discrepancies between electronic data deliverables and hard copy report forms.		